

EXHIBIT D

LIEFF, CABRASER, HEIMANN & BERNSTEIN, LLP

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SAN FRANCISCO
NASHVILLE

August 26, 2009

FIRST CLASS MAIL

Geri M. Smith
Clerk of Court
United States District Court
Northern District of Ohio
1716 Spielbush Ave.
Toledo, OH 43604

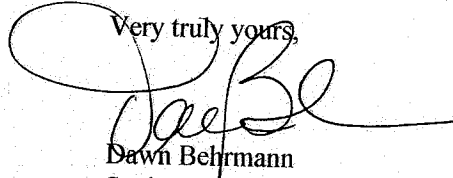
Re: Angela Beck and Martin Beck v. Bayer Corp., et al., No. 09-cv-01207
Patti Bradish and Gary Bradish v. Bayer Corp., et al., No. 09-cv-01689
Carla Leigh Brazzel v. Bayer Corporation, et al., No. 09-cv-01684
Gail Brinker and Kenneth Brinker v. Bayer Corp., et al., No. 09-cv-01682
Lauren Cathis v. Bayer Corp., No. 09-cv-01690
Anne Marie Eakins and Jonathan Eakins v. Bayer Corp., et al., No. 09-cv-01579
Brenda Ellyson v. Bayer Corp., et al., No. 09-cv-01687
Candace L. Fries v. Bayer Corp., et al., No. 09-cv-01085
Kathy Johns and William Johns v. Bayer Corp., et al., No. 09-cv-01685
Marie Claire Keultjes v. Bayer Corp., et al., No. 09-cv-01659
Saretta Main, et al. v. Bayer Corp., et al., No. 09-cv-01688
Heather Manion v. Bayer Corp., et al., No. 09-cv-01750
Marlene Meadows v. Bayer Corp., et al., No. 09-cv-01574
Lauren L. Murphy v. Bayer Corp., et al., No. 09-cv-01582
Bridget Shafer and Paul Shafer v. Bayer Corp., et al., 09-cv-01315

Dear Sir or Madam:

On behalf of Wendy R. Fleishman, counsel for Plaintiff in the related action *Candis Corey v. Bayer Corporation, et al.*, U.S.D.C. ND OH 09-cv-01984, please find enclosed for your records the Interested Person Response of Plaintiff Candis Corey for Inclusion in MDL Docket No. 2100 Moving for Centralization and for Consideration of the Northern District of Ohio Western Division as Transferee District and Memorandum of Law in Support of Interested Person Response of Candis Corey for Inclusion in MDL Docket No. 2100.

This Response was express mailed to the Clerk of the Judicial Panel of Multidistrict Litigation for filing on August 26, 2009. If you require additional copies, please let us know.

Very truly yours,

A handwritten signature in black ink, appearing to read 'Dawn Behrmann', with a large, stylized initial 'D' and a long horizontal flourish extending to the right.

Dawn Behrmann
Senior Paralegal

DB:db
Enclosures
831778.1

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SAN FRANCISCO
NASHVILLE

August 25, 2009

FIRST CLASS MAIL

Michael E. Kunz, Clerk
United States District Court
Eastern District of Pennsylvania
United States Courthouse
601 Market Street, Room 2609
Philadelphia, PA 19106-1797

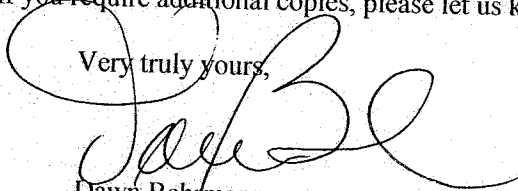
Re: Robin Adams and Thomas E. Adams v. Bayer Corp., et al., No. 09-cv-03389
Alyssa S. Britten v. Bayer Corp., et al., No. 09-cv-02086
Deborah Kay Lane-Christian and Mark D. Christian v. Bayer Corp., et al., No. 09-cv-03114
LaKollier R. Cleveland v. Bayer Corp., et al., No. 09-cv-02740
Silvia F. Galvin and Javier Galvin v. Bayer Corp., et al., No. 09-cv-02739
Adine and Kermick Gauthreaux v. Bayer Corp., et al., No. 09-cv-02238
Jennifer Grey v. Bayer Corp., et al., No. 09-cv-03555
Pamela Hamilton v. Bayer Corp., et al. No. 09-cv-00703
Danielle C. Hayat and Hadam Hayat v. Bayer Corp., et al., No. 09-cv-02753
Deborah Kay Lane-Christian and Mark D. Christian v. Bayer Corp., et al., No. 09-cv-03114
Patricia Saunders v. Bayer Corp., et al., No. 09-cv-03388

Dear Mr. Kunz:

On behalf of Wendy R. Fleishman, counsel for Plaintiff in the related action *Candis Corey v. Bayer Corporation, et al.*, U.S.D.C. ND OH 09-cv-01984, please find enclosed for your records the Interested Person Response of Plaintiff Candis Corey for Inclusion in MDL Docket No. 2100 Moving for Centralization and for Consideration of the Northern District of Ohio Western Division as Transferee District and Memorandum of Law in Support of Interested Person Response of Candis Corey for Inclusion in MDL Docket No. 2100.

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Dawn Behrman
Senior Paralegal

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August 26, 2009

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Justine Flanagan, Clerk of Court
United States District Court
Southern District of Illinois
301 West Main Street
Benton, IL 62812

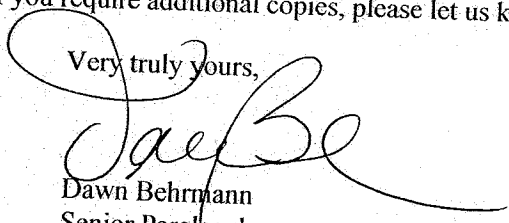
Re: Anaya Bluiett v. Bayer Corp., et al. No. 09-cv-00626
Amanda Carpenter v. Bayer Corp., et al., No. 09-cv-00642
Christina Doulbeare v. Bayer Corp., et al., No. 09-cv-00643
Brenda Hill v. Bayer Corp., et al., No. 09-cv-00567
Tamra Hicks v. Bayer Corp., et al., No. 09-cv-00602

Dear Ms. Flanagan:

On behalf of Wendy R. Fleishman, counsel for Plaintiff in the related action *Candis Corey v. Bayer Corporation, et al.*, U.S.D.C. ND OH 09-cv-01984, please find enclosed for your records the Interested Person Response of Plaintiff Candis Corey for Inclusion in MDL Docket No. 2100 Moving for Centralization and for Consideration of the Northern District of Ohio Western Division as Transferee District and Memorandum of Law in Support of Interested Person Response of Candis Corey for Inclusion in MDL Docket No. 2100.

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August 26, 2009

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Clerk of the Court
United States District Court
Western District of North Carolina
Asheville Division
100 Otis St.
Asheville, NC 28801

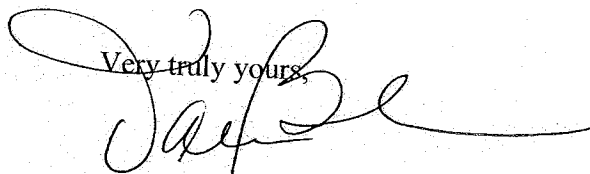
Re: Jeania Downs v. Bayer Corporation, et al., No. 09-cv-00328

Dear Sir or Madam:

On behalf of Wendy R. Fleishman, counsel for Plaintiff in the related action *Candis Corey v. Bayer Corporation, et al.*, U.S.D.C. ND OH 09-cv-01984, please find enclosed for your records the Interested Person Response of Plaintiff Candis Corey for Inclusion in MDL Docket No. 2100 Moving for Centralization and for Consideration of the Northern District of Ohio Western Division as Transferee District and Memorandum of Law in Support of Interested Person Response of Candis Corey for Inclusion in MDL Docket No. 2100.

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Clerk of the Court
United States District Court
Southern District of Iowa
PO Box 307
Council Bluffs, IA 51502

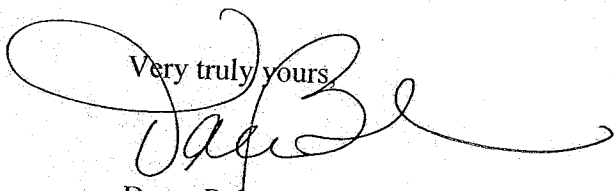
Re: Jill Fender as Special Administrator and Surviving Parent of the Estate of
Melissa A. Fender v. Bayer Corporation, et al., No. 09-cv-00024

Dear Sir or Madam:

On behalf of Wendy R. Fleishman, counsel for Plaintiff in the related action *Candis Corey v. Bayer Corporation, et al.*, U.S.D.C. ND OH 09-cv-01984, please find enclosed for your records the Interested Person Response of Plaintiff Candis Corey for Inclusion in MDL Docket No. 2100 Moving for Centralization and for Consideration of the Northern District of Ohio Western Division as Transferee District and Memorandum of Law in Support of Interested Person Response of Candis Corey for Inclusion in MDL Docket No. 2100.

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August 26, 2009

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John W. Sanfilippo, Clerk of Court
United States District Court
Eastern District of Wisconsin
125 South Jefferson St.
PO Box 24490
Green Bay, WI 54305-2490

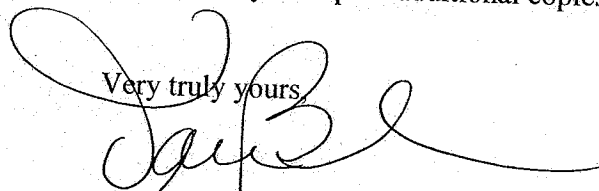
Re: Marie Becker v. Bayer Corp., et al., No. 09-cv-00663

Dear Mr. San Filippo:

On behalf of Wendy R. Fleishman, counsel for Plaintiff in the related action *Candis Corey v. Bayer Corporation, et al.*, U.S.D.C. ND OH 09-cv-01984, please find enclosed for your records the Interested Person Response of Plaintiff Candis Corey for Inclusion in MDL Docket No. 2100 Moving for Centralization and for Consideration of the Northern District of Ohio Western Division as Transferee District and Memorandum of Law in Support of Interested Person Response of Candis Corey for Inclusion in MDL Docket No. 2100.

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Dawn Behrmann
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Robert D. Dennis, Clerk of Court
United States District Court
Western District of Oklahoma
200 NW 4th St.
Oklahoma City, OK 73102

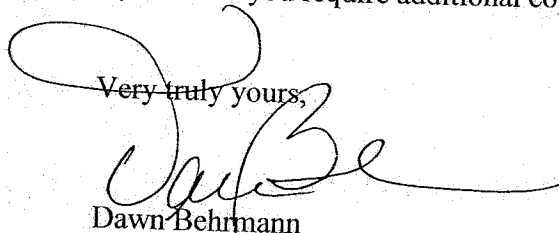
Re: Stacey L. Perry v. Bayer Corp., et al., No. 09-cv-00919

Dear Mr. Dennis:

On behalf of Wendy R. Fleishman, counsel for Plaintiff in the related action *Candis Corey v. Bayer Corporation, et al.*, U.S.D.C. ND OH 09-cv-01984, please find enclosed for your records the Interested Person Response of Plaintiff Candis Corey for Inclusion in MDL Docket No. 2100 Moving for Centralization and for Consideration of the Northern District of Ohio Western Division as Transferee District and Memorandum of Law in Support of Interested Person Response of Candis Corey for Inclusion in MDL Docket No. 2100.

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Very truly yours,


Dawn Behrmann
Senior Paralegal

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Enclosures

831691.1

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August 26, 2009

FIRST CLASS MAIL

Lawrence K. Baerman, Clerk of Court
U.S. District Court
Northern District of New York
100 S. Clinton St.
PO Box 7367
Syracuse, NY 13261

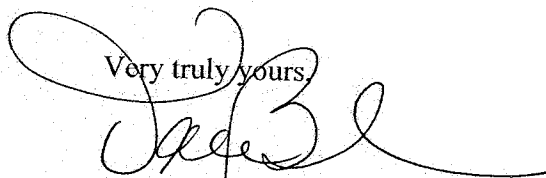
Re: Ruth Perry and John Perry v. Bayer Corporation, et al., No. 09-cv-00731

Dear Mr. Baerman:

On behalf of Wendy R. Fleishman, counsel for Plaintiff in the related action *Candis Corey v. Bayer Corporation, et al.*, U.S.D.C. ND OH 09-cv-01984, please find enclosed for your records the Interested Person Response of Plaintiff Candis Corey for Inclusion in MDL Docket No. 2100 Moving for Centralization and for Consideration of the Northern District of Ohio Western Division as Transferee District and Memorandum of Law in Support of Interested Person Response of Candis Corey for Inclusion in MDL Docket No. 2100.

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Dawn Behrmann
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Enclosures
831774.1

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Clerk of Court
U.S. District Court
Eastern District of New York
225 Camden Plaza
Brooklyn, NY 11201

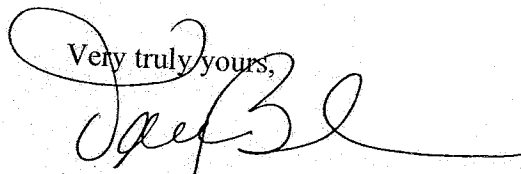
Re: Laquita O'Nekia Harel v. Bayer Corporation, et al., No. 09-cv-3639

Dear Sir or Madam:

On behalf of Wendy R. Fleishman, counsel for Plaintiff in the related action *Candis Corey v. Bayer Corporation, et al.*, U.S.D.C. ND OH 09-cv-01984, please find enclosed for your records the Interested Person Response of Plaintiff Candis Corey for Inclusion in MDL Docket No. 2100 Moving for Centralization and for Consideration of the Northern District of Ohio Western Division as Transferee District and Memorandum of Law in Support of Interested Person Response of Candis Corey for Inclusion in MDL Docket No. 2100.

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Senior Paralegal

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SAN FRANCISCO
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August 26, 2009

FIRST CLASS MAIL

Richard W. Wieking
Clerk of Court
United States District Court
Northern District of California
1301 Clay Street, Suite 400 S.
Oakland, CA 94612-5212

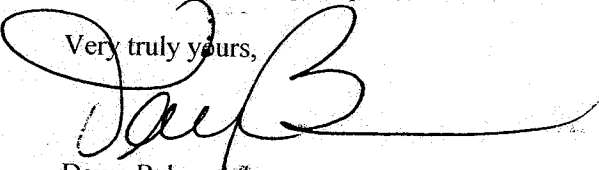
Re: April Freeman-Hollenshead and Michael C. Hollenshead v. Bayer Corp., et al.,
No. 09-cv-3152
Stephanie D. Ivey v. Bayer Corp., et al., No. 09-cv-0904
Tamera Jirbi v. Bayer Corp., et al., No. 09-cv-488829
Bridget Renee Tanner and Russell Tanner v. Bayer Corp., et al., No. 09-cv-
1558
Dawn Voss v. Bayer Corp., et al., No. 09-cv-1905
Bianca White v. Bayer Corp., et al. No. 09-cv-02417

Dear Mr. Wieking:

On behalf of Wendy R. Fleishman, counsel for Plaintiff in the related action *Candis Corey v. Bayer Corporation, et al.*, U.S.D.C. ND OH 09-cv-01984, please find enclosed for your records the Interested Person Response of Plaintiff Candis Corey for Inclusion in MDL Docket No. 2100 Moving for Centralization and for Consideration of the Northern District of Ohio Western Division as Transferee District and Memorandum of Law in Support of Interested Person Response of Candis Corey for Inclusion in MDL Docket No. 2100.

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Very truly yours,


Dawn Behrman
Senior Paralegal

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Enclosures
831665.1

**BEFORE THE JUDICIAL PANEL ON
MULTIDISTRICT LITIGATION**

In re:

YASMIN/ YAZ PRODUCTS LIABILITY
LITIGATION

MDL Docket No. 2100

**MEMORANDUM OF LAW IN SUPPORT OF INTERESTED PERSON RESPONSE OF
PLAINTIFF CANDIS COREY FOR INCLUSION IN MDL DOCKET NO. 2100 FOR
CENTRALIZATION AND FOR CONSIDERATION OF THE NORTHERN DISTRICT
OF OHIO AS TRANSFEREE DISTRICT**

Wendy R. Fleishman
LIEFF, CABRASER, HEIMANN & BERNSTEIN, LLP
250 Hudson Street, 8th Floor
New York, NY 10013
Telephone: (212) 355-9500
Facsimile: (212) 355-9592

[Additional Counsel on the Signature Page]

Attorneys for Plaintiff Candis Corey

Pursuant to Rule 7.2 of the Rules of Procedure for the Judicial Panel on Multidistrict Litigation, Candis Corey ("Movant"), Plaintiff in Corey v. Bayer Corp., et al., case no. 3:09-cv-01984, submits this memorandum of law supporting her request that the Judicial Panel on Multidistrict Litigation ("the Panel") include the Northern District of Ohio, Western Division, in those fora under consideration for transfer and centralization in this matter.

I. BACKGROUND

In July 2003, the Food and Drug Administration (the "FDA") issued a warning letter to Defendant Laboratories relating to Yasmin (drospirenone/ethinyl estradiol) Tablets developed and manufactured by Berlex Laboratories, which has since been acquired by Defendant Bayer Healthcare Pharmaceutical, Inc. A copy of that Warning Letter is attached hereto as Exhibit "A".

Defendant Bayer Healthcare Pharmaceuticals, Inc. was formerly known as Berlex, Inc., which was also formerly known as Berlex Laboratories, Inc., and is the same corporate entity as Berlex, Inc. Defendants Berlex Laboratories, Inc. and Berlex, Inc. were integrated into Bayer Healthcare AG and operate as an integrated specialty pharmaceuticals business under the new name, Bayer Healthcare Pharmaceuticals, Inc. As of January 1, 2008, Defendant Bayer Pharmaceuticals Corporation was merged into Defendant Bayer Healthcare Pharmaceuticals, Inc.

Defendant Bayer Schering Pharma AG is the current owner of the patent relating to the oral contraceptive, Yaz.

Defendant Bayer Schering Pharma AG is the current owner of the patent relating to the oral contraceptive Yasmin. Defendant Bayer Schering Pharma AG is a German chemical and pharmaceutical company that is headquartered in Leverkusen, North Rhine-Westphalia, Germany. Defendant Bayer AG is the third largest pharmaceutical company in the world.

Defendant Bayer AG is the parent holding company of all other named defendants. (hereinafter collectively referred to as "Bayer").

Yasmin received FDA approval first in 2001. It is a combination of drospirenone, a progestin, and ethinyl estradiol, an estrogen. Yaz received approval from the FDA in 2006 and is essentially the same as Yasmin, with the only difference being a slightly smaller amount of ethinyl estradiol. Yaz and Yasmin are indicated for the prevention of pregnancy in women who elect to use an oral contraceptive. Combination birth control pills are referred to as combined hormonal oral contraceptives. The difference between Yasmin and Yaz and other birth control pills on the market is that drospirenone has never before been marketed in the United States and is unlike other progestins available in the United States.

According to IMS Health Data, in 2008, Yaz sales accounted for \$616 million dollars. In 2007, Yaz sales accounted for \$262 million. See <http://www.mmm-online.com/Bayer-runs-corrective-Yaz-ad-agrees-to-preclearance/article/127205>.

In April 2002, the British Medical Journal reported that the Dutch College of General Practitioners recommended that older second generation birth control pills be prescribed in lieu of Yasmin as a result of 40 cases of venous thrombosis among women taking Yaz/Yasmin. In February 2003, a paper entitled Thromboembolism, associated with the new contraceptive Yaz/Yasmin, was published in the British Medical Journal detailing a Netherlands Pharmacovigilance Centre report of additional reports of thromboembolism where Yaz/Yasmin was suspected as the cause, including two deaths.

Defendants have twice been warned by the FDA, in 2003 and 2008, for misleading the public through the use of television advertisements which overstate the efficacy of the drugs and minimize the serious risks associated with the drugs.

The use of Yaz/Yasmin has a prothrombotic effect resulting in the development of thromboses, such as pulmonary emboli and deep vein thrombosis. The Bayer Defendants failed to recognize the correlation between the use of these products and increased thrombosis formation despite the wealth of scientific information available. The Bayer Defendants knew or should have known about the correlation between Yaz/Yasmin use and a prothrombotic effect and still promoted, sold, advertised, and marketed the use of their products without sufficient warnings. Yaz/Yasmin's use of drospirenone, a diuretic, creates unique risks for compared to other oral contraceptives. These risks include heart arrhythmias, myocardial infarction, and other adverse cardiovascular events, including sudden death. The diuretic is also known to cause problems with the gallbladder; the problems sometimes require surgical intervention. The diuretic also causes kidney stone formation.

The Bayer Defendants did not provide adequate warnings to doctors, the health care community and the public about the risk of serious adverse events that are described in this complaint. As a result of the manufacturing, marketing, advertising, promotion, distribution, and sale of Yaz/Yasmin without adequate warnings about the risks of serious injuries, Plaintiff Candis Corey has sustained severe and permanent personal injuries.

In light of these injuries and damages, Movant filed an action in the Northern District of Ohio, Western Division, on August 24, 2009, against the Bayer Defendants. Plaintiff has alleged, *inter alia*, that the Bayer Defendants designed, manufactured, marketed, distributed and sold Yaz and Yasmin Tablets that are defective, and that the Bayer Defendants concealed knowledge of the defect for some period. Further, Movant alleged that as a direct and proximate result of the defective products being placed in the stream of commerce by the Bayer

Defendants, Movant suffered a risk of possible death, and did suffer severe injury and disability, including physical and mental pain and suffering, as well as economic loss.

Plaintiff is presently aware of more than fifty (50) other related actions that have been filed in various district courts throughout the United States. These actions all name the Bayer Defendants as defendants and assert substantially similar claims and seek almost identical relief. These actions are set forth in the schedule of actions, attached to the Fries Joinder Motion.

Centralization of these actions is appropriate because they involve common factual questions, common questions of law, and will require common discovery. Transfer for centralization will further the efficient and expeditious resolution of this matter and will promote the just and efficient conduct of these actions.

II. ARGUMENT

A. Centralization Of Yasmin/Yaz Cases For Coordinated Pretrial Proceedings Will Further The Goals of § 1407.

For all the reasons set forth in part II.A of the Motion of Candace Fries, et al. for Transfer and Consolidation of All Related Actions Pursuant to 28 U.S.C. § 1407, centralization of pretrial proceedings will further the goals of § 1407. To avoid duplicative and unnecessary briefing, Movant will not restate those reasons here.

B. The Action Should Be Transferred To The Northern District of Ohio And In Particular To The Honorable James G. Carr.

The key factors that this Panel considers in making the determination of an appropriate forum are:

1. The location of parties, witnesses and documents;
2. The accessibility of the proposed transferee district to parties and witnesses; and
3. The respective case lists of proposed transferee district courts.

See In re Corn Derivatives Antitrust Litigation, 486 F. Supp. 929, 931-32 (J.P.M.L. 1980).

Centralization of these actions in the Northern District of Ohio for centralized pretrial proceedings will best serve the convenience of the parties, the witnesses and the interests of justice. There are currently 15 related cases pending in the Northern District of Ohio, including Brinker v. Bayer Corp., et al., Case No. 3:09-cv-01682, filed on July 21, 2009, which has been assigned to the Honorable James G. Carr.

C. **Convenience Of The Parties And Witnesses Favors The Northern District Of Ohio.**

Defendant Bayer Healthcare Pharmaceutical, Inc., Berlex Laboratories and Berlex, Inc. are headquartered in central New Jersey. Ohio is equally accessible for all parties, their counsel, and the witnesses. Therefore, the Northern District of Ohio at Western Division is a convenient location. Accordingly, the convenience of the parties and witnesses favors transfer to the Northern District of Ohio.

D. **The Northern District Of Ohio Has Previously Been Selected As The Transferee Forum And Judge For Other Complex Product Liability Cases.**

Demonstrating its confidence in the Northern District of Ohio's capabilities, the Panel has already selected this district as the transferee forum for other complex product liability cases. This Panel has often looked at jurists' experience and docket considerations to determine the transferee district. See, e.g., In re Celexa and Lexapro Products Liability Litigation, MDL-1736 (J.P.M.L. February 16, 2006) (transferring cases where parties were geographically dispersed to the Eastern District of Missouri to "jurists experienced in complex multidistrict litigation sitting in centrally located districts with the capacity to handle the matter"); In re Teflon Products Liability Litigation, MDL-1733 (J.P.M.L. February 21, 2006) (transferring cases where parties were geographically dispersed to Southern District of Iowa to a court that "enjoys general docket conditions permitting the Panel to effect the Section 1407 assignment to a court

with the present resources to devote to the pretrial matters that this docket is likely to require”); In re Viagra Products Liability Litigation, MDL-1724 (J.P.M.L. February 21, 2006) (transferring cases where parties were geographically dispersed to the District of Minnesota to a “jurist experienced in complex multidistrict litigation and sitting in a district with the capacity to handle this litigation”); In re Bextra and Celebrex Marketing, Sales Practices and Price Liability Litigation, MDL-1699 (J.P.M.L. September 6, 2005) (transferring cases where parties were geographically dispersed to the Northern District of California to a jurist who had “experience in complex multidistrict litigation sitting in a district with the capacity to handle this litigation”). It is clear that the parties involved in this litigation are dispersed nationwide as they were in each of these complex products liability matters. The product at issue in this case was sold and distributed nationwide and, indeed, worldwide.

The Panel has previously recognized the ability of the Honorable James G. Carr to manage a complex pharmaceutical case and the suitability of the Northern District of Ohio to serve as the § 1407 transferee forum. See, e.g., In re Contaminated Heparin products Liability Litigation (J.P.M.L. 1953) (transferring case to Judge Carr recognizing that the Northern District of Ohio is well equipped with the resources that this docket is likely to require).

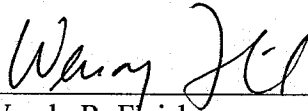
Centralization in the Northern District of Ohio permits the Panel to effect the § 1407 assignment to a court that (1) is not currently overtaxed with other multidistrict dockets, (2) possesses the necessary resources to be able to devote the substantial time and effort to pretrial matters that this complex docket is likely to require, and (3) to a transferee judge who can steer this litigation on a steady and expeditious course. The Northern District of Ohio meets all of these criteria and is an appropriate transferee forum.

III. CONCLUSION

Centralization of these actions and any other subsequently filed related cases for pretrial proceedings will serve the best interests of justice by providing a single forum in which the legal rights of each of the litigants can be adjudicated fairly and efficiently. For the foregoing reasons, Movant respectfully requests that the Panel consider transfer of the MDL No. 2100 action to the Northern District of Ohio, Western Division, and the Honorable James G. Carr.

Dated: August 26, 2009

Respectfully submitted,

By: 
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Counsel for Plaintiff Candis Corey



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

TRANSMITTED BY FACSIMILE

Nancy Konnerth
Associate Director, Advertising and Labeling
Drug Regulatory Affairs
Berlex Laboratories
340 Changebridge Road
P.O. Box 1000
Montville, NJ 07045-1000

RE: NDA 21-098
Yasmin (drospirenone/ethinyl estradiol) Tablets
MACMIS ID# 11730

Dear Ms. Konnerth:

This letter notifies Berlex Laboratories (Berlex) that the Division of Drug Marketing, Advertising, and Communications (DDMAC) has identified a direct-to-consumer (DTC) broadcast advertisement (TV ad) for Yasmin (drospirenone/ethinyl estradiol) Tablets that is misleading and in violation of the Federal Food, Drug, and Cosmetic Act (Act) and applicable implementing regulations. Specifically, the 60-second TV ad entitled "Goodbye Kiss" is misleading because it makes implied clinical superiority claims to other combination oral contraceptives and minimizes the important risk information that distinguishes Yasmin from other combination oral contraceptives. As a result, the TV ad raises significant public health and safety concerns.

Background

Yasmin is a combination oral contraceptive ("COC" or "birth control pill") prescription drug product. Yasmin, like any oral contraceptive, is associated with increased risks of several serious conditions (including myocardial infarction, thromboembolism, stroke, hepatic neoplasia, gallbladder disease, and hypertension), although the risk of serious morbidity or mortality is very small in healthy women without underlying risk factors. The risk of morbidity and mortality increases significantly in the presence of other underlying risk factors such as hypertension, hyperlipidemias, obesity, and diabetes. (See the WARNINGS section of the Yasmin approved physician labeling (PI))

Yasmin contains the estrogen ethinyl estradiol and the progestin drospirenone. Drospirenone has antimineralocorticoid properties, which means that it can work against the body's normal mechanism for regulating salt and water balance, a situation that can lead to hyperkalemia in high risk patients, resulting in potentially serious heart and health problems. This additional risk is described in the Bolded Warning of Yasmin's PI:

Nancy Konnerth.
Berlex Laboratories
NDA 21-098

2

Yasmin contains 3 mg of the progestin drospirenone that has antimineralocorticoid activity, including the potential for hyperkalemia in high-risk patients, comparable to a 25 mg dose of spironolactone [a potassium-sparing diuretic]. Yasmin should not be used in patients with conditions that predispose to hyperkalemia (i.e., renal insufficiency, hepatic dysfunction and adrenal insufficiency). Women receiving daily, long-term treatment for chronic conditions or diseases with medications that may increase serum potassium, should have their serum potassium level checked during the first treatment cycle. Drugs that may increase serum potassium include ACE inhibitors, angiotensin -- II receptor antagonists, potassium-sparing diuretics, heparin, aldosterone antagonists, and NSAIDs.

Consequently, Yasmin can exacerbate serious heart and health problems, in addition to the potential problems common to all COCs. Women taking Yasmin must be concerned about drug interactions that will increase potassium, in addition to the drug interactions common to all COCs. Therefore, these women and their healthcare providers must weigh Yasmin's additional health risks when considering Yasmin over COCs without drospirenone.

Misleading Efficacy and Safety Presentations

Prescription drug ads are false or misleading if they contain a drug comparison that represents or suggests that a prescription drug is more effective or safer than another drug when it has not been demonstrated to be safer or more effective by substantial evidence or substantial clinical experience (21 CFR 202.1(e)(6)(ii)). The TV ad misleadingly overstates the efficacy and safety of Yasmin by suggesting that Yasmin is unique and therefore clinically superior to other birth control pills because it contains the chemically different progestin drospirenone. The unifying theme of the ad, typified by the tagline "Ask about Yasmin, and **the difference a little chemistry can make**" (emphasis added) suggests that Yasmin is better than other birth control pills because of drospirenone and the way in which it is metabolized in the body. This "chemistry" difference is presented as a product benefit. FDA is not aware of substantial evidence or substantial clinical experience demonstrating that Yasmin is superior to other COCs or that the drospirenone in Yasmin is clinically beneficial. On the contrary, FDA is aware of the added clinical risks associated with drospirenone as communicated in the Warnings/Bolded Warning, and Precautions/Drug Interactions sections of the PI.

Specifically, the following claims in the TV ad address Yasmin's efficacy: "You don't settle when it comes to the guy...so why settle when it comes to the pill? **The Yasmin birth control pill uses a different kind of hormone. One that may work with your body chemistry.** Yasmin is over 99% effective at preventing pregnancy. So when you're looking for the right pill, ask your doctor about the difference a little chemistry can make." (emphasis added) These claims are misleading because they suggest that Yasmin's "different kind of hormone" offers unique "chemistry" benefits and that this difference contributes to the high rate of drug efficacy. Moreover, these claims are misleading because they imply superiority to other COCs (and thus do not offer the same product benefits as Yasmin Tablets) when such has not been demonstrated by substantial evidence or substantial clinical experience. Finally, these claims are misleading because they misrepresent Yasmin's mechanism of action by stating that Yasmin "uses a different kind of hormone. One that may work with your body

Nancy Konnerth.
Berlex Laboratories
NDA 21-098

3

chemistry." However, COCs, including Yasmin, prevent ovulation by working against the usual body chemistry of a woman of childbearing potential by suppressing endogenous gonadotropins and, thereby, inhibiting ovulation and altering other changes associated with the menstrual cycle.

In addition, the statement "Yasmin contains a different progestin, which may increase potassium" is misleading because the "may increase potassium" disclosure fails to communicate that the potential to increase potassium is a risk. Furthermore, consumers may interpret the statement as a product benefit claim rather than a risk disclosure due to the overall positive message that Yasmin's "chemistry" is a product benefit. The ad conveys this positive message to consumers, notwithstanding the disclosure that "You should not take Yasmin if you have kidney, liver, or adrenal disease," because the "different kind of hormone" and "chemistry" messages are never clearly identified as potentially leading to increased potassium levels or that increased serum potassium can be dangerous. This important risk information is in a Bolded Warning in the PI and clearly conveyed in the Yasmin Brief Summary Patient Package Insert and in the Detailed Patient Package Insert:

Yasmin is different from other birth-control pills because it contains the progestin drospirenone. Drospirenone may increase potassium. Therefore, you should not take Yasmin if you have kidney, liver, or adrenal disease because this could cause serious heart and health problems. Other drugs may also increase potassium. If you are currently on daily, long-term treatment for a chronic condition with any of the medications below, you should consult your healthcare provider about whether Yasmin is right for you, and during the first month that you take Yasmin, you should have a blood test to check your potassium level.

Thus, by failing to add the necessary context to clarify that increased blood potassium is a safety risk rather than a clinical benefit, the ad misleadingly represents or suggests that Yasmin is safer than has been demonstrated by substantial evidence or substantial clinical experience.

In summary, the TV ad not only misleads consumers about the efficacy of Yasmin, the ad also minimizes important context about the health risks of the drug.

Conclusions and Requested Actions

Berlex should immediately discontinue the TV ad and all other promotional materials and activities for Yasmin that contain the same or similar violative presentations. Berlex should submit a written response to DDMAC on or before July 24, 2003, describing its intent and plans to comply with the above. In its letter to DDMAC, Berlex should include the date on which these and other similarly violative materials were discontinued.

Berlex should direct its response to the undersigned by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising, and Communications HFD-42, Rm. 8B-45, 5600 Fishers Lane, Rockville, Maryland 20857.

Nancy Konnerth.
Berlex Laboratories
NDA 21-098

4

In all future correspondence on this matter, please refer to MACMIS ID# 11730 as well as the NDA number. DDMAC reminds Berlex that only written communications are considered official.

Sincerely,

{See appended electronic signature page}

Joan Hankin
Consumer Promotion Analyst
Division of Drug Marketing,
Advertising, and Communications

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Joan Hankin

7/10/03 03:40:53 PM

YASMIN
Pharmaceuticals, Inc.

"Goodbye Kiss" :60 5/14/03
pg. 1 of 4

5/16/03

Directors Note: This commercial is all about showing the chemistry between two people. We use the wrong guy to demonstrate how special it is when you find the right guy. When we reveal the Yasmin girl finally finding the right guy, the goal is to play up the drama of the chemistry between them.



MALE 1:

I felt a real connection tonight.



YASMIN
Bayer HealthCare Pharmaceuticals

"Goodbye Kiss" :60 5/14/03
pg. 2 of 4



ANNCR 1:

You don't settle when it comes to the guy...



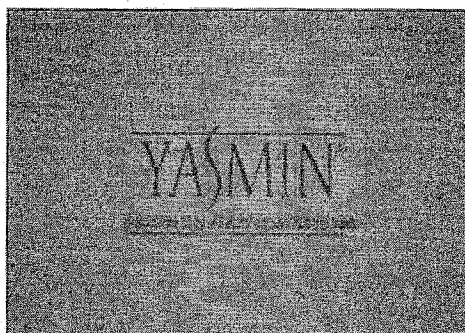
MALE 2:

You rock, babe!



ANNCR 1:

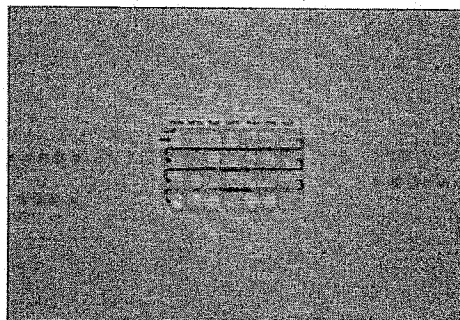
...so why settle when it comes to the pill?



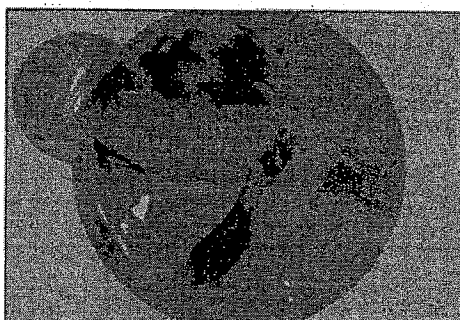
The Yasmin birth control pill uses
a different kind of hormone.
One that may work with your body chemistry.

YASMIN
Bayer HealthCare Pharmaceuticals

"Goodbye Kiss": 60 5/14/03
pg. 3 of 4



Yasmin is over 99% effective at preventing pregnancy.



So when you're looking for the right pill,



Ask your doctor about the difference
a little chemistry can make.

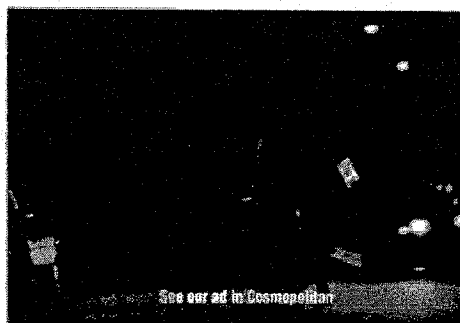


ANNCR 2:

Yasmin contains a different progestin, which may increase potassium. You should not take Yasmin if you have kidney, liver or adrenal disease.

YASMIN
A prescription birth control pill

"Goodbye Kiss" :60 5/14/03
pg. 4 of 4



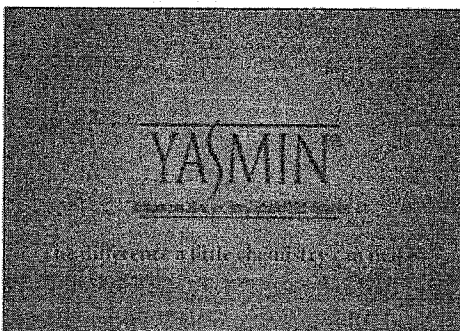
Tell your doctor if you are on daily,
long-term treatment with NSAIDs



like ibuprofen or Naproxen for a chronic
condition like arthritis, or taking
cardiovascular medications, or Heparin.
Birth control pills do not protect against HIV
or sexually transmitted diseases.



Women especially over 35 should not smoke.
Serious risks, occurring infrequently,
include blood clots, stroke and heart attack.



ANNCR 1:

Ask about Yasmin, and the difference a little
chemistry can make.


JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

TO: Judicial Panel on Multidistrict Litigation
Thurgood Marshall Federal Judiciary Building
One Columbus Circle, N.E.
Room G-255
Washington, D.C. 20002
Panel Fax No.: (202) 502-2888

MDL No. 2100 — In re Yasmin/Yaz Products Liability Litigation

CERTIFICATE OF SERVICE

Service of the foregoing Interested Person Response Of Plaintiff Candis Corey For Inclusion In MDL Docket No. 2100 for Centralization and for Consideration of the Northern District of Ohio as Transferee District and Memorandum of Law in Support of Interested Person Response of Plaintiff Candis Corey For Inclusion in MDL Docket No. 2100 was served upon all individuals in the attached Panel Service List and Supplemental Proof of Service List by mailing a true and correct copy thereof by United States mail, postage prepaid, this 26th day of August, 2009.



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**3397-0001: YAZ PRODUCT LIABILITY LITIGATION-General Matters -
MDL 2100**

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**3397-0001: YAZ PRODUCT LIABILITY LITIGATION-General Matters -
MDL 2100**

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